UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,322	10/24/2006	Mesut Muyan	21108.0032U2	9900

23859 7590 04/03/2008

NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
04/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,322	MUYAN ET AL.	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 7-9, 11-13, 15-23, 30, 50, 51, 55, 58-61, 64, 67-86, 88, 92,and 94* is/are pending in the application.

4a) Of the above claim(s) *3, 16, 18, 20, 22, 50, 51, 55, 58-61, 64, and 67-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-9,11-13,15,17,19,21,23,30,86,88,92 and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1, 2, 7-9, 11-13, 15-23, 30, 86, 88, 90, 92 and 94) and SEQ ID NOs 9, 23, and 24, in the reply filed on 2/4/2008 is acknowledged. The traversal is on the ground(s) that: 1) the claims recite a special technical feature not taught by the prior art (i.e. Muyan et al, 2001) and thus should not be restricted; 2) certain restrictions are "nonsensical" or "inoperable"; 3) applicants should be allowed. to prosecute a reasonable number of species; 4) 36 CFR 1.475(b) states that claims to different categories of invention will be considered to have unity of invention; 5) according to MPEP 1850, unity of invention is to be considered only with independent claims, and if the independent claims avoid the prior art, no problem of lack of unity is found with claims dependent from the independent claim.

This is not found persuasive because regarding 1), the claims do not share a special technical feature because that technical feature is taught by the prior art, i.e. Muyan et al (2001). Applicants arguments that Muyan et al teach a "homofusion" of ERα is not persuasive because the homofusion of ERα taught by Muyan et al is within the scope of instant claim 1, at the least. The claims do not require that the DNA binding domains of the fusion protein be different from each other. Rather, the specification indicates that they may be the same. See, for example, the protein "CDC" in Fig. 1a, which comprises the two C domains of ERα separated by a hinge domain "D". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the DNA binding domains are different) are not recited in the rejected claim(s). Although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, Muyan et al teach that the DNA binding domains may be different, see Fig. 5A, in particular the α-AF2 or AF2-α proteins.

Regarding 2), the Examiner did not draft the claims, and the restriction was based upon the plain meaning of the claims, i.e. it is difficult to misinterpret, for example, claim 4 (prior to amendment), which recited "The hinge domain of claim 1..." as requiring any other limitations than a composition comprising a hinge domain. That is, the original claims broadened the scope of the parent claim as they required less structure than the parent claim. In any event, the amendment of claims 4 and 5 renders these claims as proper dependent claims, and these arguments moot. As such, they are rejoined to Group I.

Further regarding 2), a reading of the claims reveals that selection of a particular DNA binding domain SEQ ID NO does not force the claims to recite a "homodimer" rather than a "heterodimer". For example, claim 88 (dependent from claim 1) recites that the second DNA binding domain be a particular SEQ ID NO. There are no limitations placed on the sequence of the first DNA binding domain, thus it appears heterodimers are within the scope of the claims. The same is true for claims directed to a particular DNA binding site (e.g. claims 15-19 only set forth limitations on first or second half sites, not both).

Regarding 3), a reading of the claims reveals that numerous species are recited, for example, in claims 2 and 8. The restriction between distinct SEQ ID NOs is not held to be a species restriction for reasons of record, i.e. the SEQ ID NOs are distinct inventions, and the distinct inventions lack unity in light of the parent claim being taught by the prior art.

Regarding 4), the recited Rule 1.475 also states, in (a), that different groups of inventions will have unity of invention only when a special technical feature links the inventions. Thus, the Groups of the instant application lack unity of invention for reasons set forth in the restriction requirement, and above. Furthermore, sections (b) and (c) of the Rule set forth reasons why categories of invention might lack unity, not that inventions lacking unity for the reason set forth in (a) should be rejoined and examined.

Regarding 5), claim 1 does not avoid the prior art for reasons set forth above and below. Further, the cited passage of MPEP 1850 details that independent claims should be considered only in the first place (emphasis added). Thus, because claim 1 does not avoid the prior art, further lack of unity regarding independent claims was considered.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 16, 18, 20, 22, 50, 51, 55, 58-61, 64, and 67-85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 16, 18, 20, 22 are not drawn to the elected binding site, i.e. SEQ ID NO: 9, which does not comprise half sites, SEQ ID NO: 1, direct repeats, and appears to have binding half sites separated by three nucleotides. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/4/2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 13 recite the limitation "the transcription factor ER" in line 1. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7-9, 11-13, 15,, 17, 19, 21, 23, 30, 86, 88, 92 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Muyan et al (2001, of record) as evidenced by the Genbank Entry for Accession number P03372 (human estrogen receptor alpha, created July, 1986).

Muyan et al disclose in Fig. 1A an estrogen receptor (ERα) homodimer fusion protein that comprises two C domains (DNA binding domains) separated by a ERα D domain (a hinge domain by applicants definition, see page 37, Fig. 1A of the instant disclosure, and claim 5). The ER homodimer fusion protein of Muyan et al bound the ERE DNA sequence, see Fig. 1C and D. The DNA sequence in Fig. 1C teaches a DNA binding site (bracketed) for the fusion protein comprising SEQ ID NO: 9, i.e. GGTCANNNTGACC and SEQ ID NO: 2, i.e. AGGTCA. Muyan et al teach that this binding site is an inverted repeat (page 253, second

column), and that this ERE is recognized by ER as a dimer, i.e. the ERE comprises half-sites as described in the specification (page 42, line 20 to page 43) wherein each ER monomer binds one half site of, for example, SEQ ID NO: 9 wherein the half sites are separated by a three nucleotide spacer, i.e. "nnn" or "gcg" as taught by Muyan et al (page 253, second column, first full ¶). Regarding claim 19, it is considered that the ERE of Muyan et al teaches SEQ ID NO: 2 as the second half site in the 3' - 5' direction in Fig. 1C, for example. The ERα domains of Muyan et al were based on the sequence reported by Green et al (1986, Reference 1 in the GenBank entry below), see page 253, first column. The GenBank entry (P03372) for the human ERα teaches that the sequence of Green et al comprises SEQ ID NO: 23 (claims 86 and 88) from residues 176-244 and SEQ ID NO: 24 (claims 92 and 94) from residues 251-301. Thus, absent evidence to the contrary, the ERα fusion protein of Muyan et al inherently comprises a DNA binding domain (either first or second binding domains) comprising SEQ ID NO: 23 and a hinge domain of SEQ ID NO: 24. Muyan et al further teach that the fusion proteins may comprise DNA binding domains from distinct DNA binding proteins, such as a fusion between ERα and an ERα variant termed AF-2 with decreased transcriptional activity. See page 258, first column, first full ¶ and Fig. 5 A. Thus, the teachings of Muyan et al are not limited to "homodimers".

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915.

The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Burkhart
Art Unit 1633

/Michael Burkhart/
Primary Examiner, Art Unit 1633